

### **REMARKS/ARGUMENTS**

By the present amendment, Claim 1 has been amended to incorporate the subject matter of previous claim 2, which has been canceled. Claim 13 has also been canceled as directed to a non-elected species. Claims 5-7, 10 and 16 have been amended to depend from claim 1 and claim 20 has been amended to correct a typographical error. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. The amendment does not contain new matter and its entry is respectfully requested.

The Official Action dated July 13, 2004 has been carefully considered. It is believed that the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

### **Restriction/Election**

The Examiner has acknowledged Applicant's election of the subject matter of Group I and states that the claims have not been amended to reflect the elected subject matter. In response, claim 1 has been amended in order to specify that the agent is a nucleic acid sequence comprising a sequencing encoding a TAP molecule as requested by the Examiner. In addition, claim 13 has been canceled as being drawn to a non-elected invention. However, Applicant does note that the Examiner has stated in the restriction requirement that claim 1 links inventions I and II and upon allowance of Claim 1 the restriction requirement as to the non-elected inventions shall be withdrawn and the non-elected claims will be entitled to examination. As such, Applicant reserves the right to pursue the scope of original claim 1 and to re-introduce claim 13 at a later date.

### **Double Patenting**

The Examiner has rejected claims 1-2, 4-5, 7, 9, and 14-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10

of United States Patent No. 6,361,771. A terminal disclaimer will be filed once the Applicant receives an indication that the present claims are allowable.

**35 USC §112, First Paragraph**

The Examiner has objected to Claims 1-12, and 14-20 under 35 USC §112, first paragraph, as not providing enablement for methods of enhancing any type of immune response to tumor cells comprising transfecting tumor cells *ex vivo* or *in vivo* with any nucleic acid encoding TAP-2, or methods of enhancing any type of immune response to any viral antigen in a cell comprising transfecting the cell *in vitro* or *in vivo* with TAP-1 or TAP-2 alone. We respectfully disagree with the Examiner for the reasons that follow.

Applicant has shown that administering a TAP molecule can enhance an immune response to many different types of antigens including tumor antigens as well as viral antigens. With respect to tumor antigens, Applicant has shown the enhancement of immune response to small cell lung carcinoma cells, prostate cancer cells as well as melanoma cells. With respect to viral antigens, Applicant has shown the enhancement of immune response to VSV peptides as well as SENDAI-virus peptides (see example 19). As a result, the working examples provided in the application provide sufficient evidence to enable one skilled in the art to practice the invention with any antigen.

Applicants submit that it would place an undue burden on the Applicants for them to test every possible antigen. Further, U.S. caselaw relating to biotechnology inventions has held that Applicants are not required to disclose every species encompassed by their claims even in an unpredictable art (97 F. 2d at 496; 20 USPQ 2d at 1445).

The Examiner has also queried the tumor evidence stating that it is only enabling for exogenous administration of the TAP molecule or the *in vivo* administration of the TAP molecule in a vaccinia virus. We respectfully submit that these are just two embodiments of how the invention can be performed and one of skill in the art could readily administer the TAP molecule using other vectors or by other modes of

administration. In this regard, we refer to page 16, line 6 through 14 as well as page 20, line 18 through to page 21, line 19 of the application.

The Examiner also states that the specification fails to provide an enabling disclosure for a "gene inducible by tapasin". We respectfully disagree as tapasin is a known molecule and one of skill in the art can readily determine whether or not a gene is induced by tapasin.

The Examiner has also rejected claim 10 under 35 USC §112, first paragraph, as not containing an adequate written description of the invention. Claim 10 depends from claim 1 and is directed towards a specific embodiment of the invention wherein a further factor or gene is administered with the TAP molecule. The molecules listed in claim 10 are known molecules and readily available to one of skill in the art. Further, one of skill in the art could readily determine whether or not a gene is inducible by tapasin.

In view of the foregoing, we respectfully request that the objections to the claims under 35 USC §112, first paragraph be withdrawn.

#### **35 USC §112, Second Paragraph**

The Examiner has objected to claims 1-12 and 14-20 under 35 USC §112, Second Paragraph as being incomplete. In response, claim 1 has been amended in order to add the phrase "wherein administration of the agent enhances the immune response to the antigen".

In view of the foregoing, we respectfully request that the objections to the claims under 35 USC §112, second paragraph be withdrawn.

#### **35 USC §102**

The Examiner has objected to claims 1-5, 7-8, 16 and 19 under 35 USC §102(b) as being anticipated by Spies et al. (Nature, vol. 355, 644-646, 1992). We respectfully disagree with the Examiner for the reasons that follow.

The Examiner states that Spies et al. teaches the enhancement of a CTL response following administration of TAP-1 to the cells *in vitro*. However, this statement is inconsistent with the statement Examiner makes with regard to Spies et al. on page 6 of the office action. In particular, the Examiner states:

“Spies et al. transfected 721.174 cells, which have a deletion in both TAP genes, with TAP-1 (PSF-1) and showed that TAP-1 alone was incapable increasing surface expression of MHC class I (Spies et al., (1991) Nature, Vol. 351, page 323, abstract and Figure 1)” (emphasis ours).

Therefore, as the Examiner as noted, Spies et al. does not teach the present invention. In fact, Spies et al. teaches away from the present invention as acknowledged by the Examiner.

The Examiner has objected to claims 1-4, 6-8, 16 and 19 under 35 USC §102(b) as being anticipated by Powis et al. (Nature, vol. 354, 528-531, 1991). We respectfully disagree with the Examiner for the reasons that follow.

The Examiner states that Powis et al. teaches the enhancement of CTL response against a tumor by administration of TAP-2 to the cells *in vitro*. However, this statement is inconsistent with the statement that the Examiner makes with respect to Powis et al. on page 6 of the office action which states:

“As Povis [sic] et al states “...the integrity of both transporter polypeptides is required for any significant class I membrane expression or cytosolic peptide presentation. This conclusion is consistent with a model in which the two transporter polypeptides are required to associate in order to form a functional heterodimer “(Povis [sic] et al., ((1991), Nature, Vol. 354, page 531, paragraph 2).”

As a result, Powis et al. does not teach the claimed invention and in fact teaches away from the present invention.

In view of the foregoing, we respectfully request that the objections to the claims under 35 USC §102(b) be withdrawn.

**Fees**


We have enclosed a cheque in the amount of \$510.00, in respect of (1) a three month extension of time fee (small entity). A petition for a three month extension of time is enclosed in duplicate.

The Commissioner is hereby authorized to charge any deficiency in fees (including any claim fees) or credit any overpayment to our Deposit Account No. 02-2095.

In view of the foregoing, we submit that the application is in order for allowance and an early indication to that effect would be greatly appreciated. Should the Examiner like to discuss the matter, she is kindly requested to contact Micheline Gravelle at 416-957-1682 at her convenience.

Respectfully submitted,

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